

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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CLYDE OWEN,

Plaintiff,

Index No.:
07 CV 7424

-against-

ANSWER

BRISTOL-MYERS SQUIBB COMPANY, and
SCHERING CORPORATION,

Defendants.

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Defendant Bristol-Myers Squibb Company (“BMS”) by and through its attorneys, SEDGWICK, DETERT, MORAN & ARNOLD LLP, as and for its ANSWER to Plaintiff’s Complaint, states and alleges upon information and belief as follows:

AS AND FOR AN ANSWER TO THE NATURE OF THE ACTION

FIRST: The allegations of paragraph 1 are denied.

SECOND: The allegations of paragraph 2 are denied.

THIRD: The allegations of paragraph 3 are denied.

FOURTH: The allegations of paragraph 4 are denied.

FIFTH: The allegations of paragraph 5 are denied as alleged except BMS admits that it manufactured, sold and distributed Tequin® (Gatifloxacin) in accordance with its Food and Drug Administration approved labeling in the State of Arkansas and elsewhere.

SIXTH: The allegations of paragraph 6 are denied.

AS AND FOR AN ANSWER TO PARTIES

SEVENTH: It is admitted that the allegations of paragraph 7 are sufficient to bring this matter within the jurisdiction of this court except BMS is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning plaintiff's alleged residence and administration of Tequin®. The remaining allegations of paragraph 7 are denied.

EIGHTH: The allegations of paragraph 8 are denied except that BMS admits that it is a Delaware corporation authorized to do business in the State of Arkansas and that it manufactured, sold and distributed Tequin® (Gatifloxacin) in accordance with its Food and Drug Administration approved labeling and that Tequin® (Gatifloxacin) is an antibacterial agent.

NINTH: The allegations of paragraph 9 are denied for lack of sufficient information to justify a belief therein.

AS AND FOR AN ANSWER TO GENERAL ALLEGATIONS

TENTH: The allegations of paragraph 10 are denied.

ELEVENTH: The allegations of paragraph 11 are denied for lack of sufficient information to justify a belief therein. Defendant respectfully refers to the medical records and pharmacy records for plaintiff as to the circumstances surrounding the medical care and treatment rendered and plaintiff's alleged use of the product.

TWELFTH: The allegations of paragraph 12 are denied.

THIRTEENTH: The allegations of paragraph 13 are denied as alleged except BMS admits that it manufactured, sold and distributed Tequin® (Gatifloxacin) in accordance with its Food and Drug Administration approved labeling and that Tequin® (Gatifloxacin) is an antibacterial agent.

FOURTEENTH: The allegations of paragraph 14 are denied as alleged except BMS admits that it manufactured, sold and distributed Tequin® (Gatifloxacin) in accordance with its Food and Drug Administration approved labeling in the State of Arkansas.

FIFTEENTH: The allegations of paragraph 15 are denied.

SIXTEENTH: Answering paragraph 16 of plaintiff's complaint, defendant admits that the Food and Drug Administration first approved the New Drug Application for Tequin® (Gatifloxacin) on December 17, 1999, and that Tequin® (Gatifloxacin) was sold for various uses in accordance with its Food and Drug Administration approved labeling in the State of Arkansas and elsewhere.

SEVENTEENTH: The allegations of paragraph 17 are denied as alleged except that BMS admits that it sold Tequin® (Gatifloxacin) for various uses in accordance with its Food and Drug Administration approved labeling in the State of Arkansas and elsewhere and refers to the Food and Drug Administration approved Tequin® labeling for information concerning approved product indications.

EIGHTEENTH: The allegations of paragraph 18 are denied.

NINETEENTH: The allegations of paragraph 19 are denied.

TWENTIETH: The allegations of paragraph 20 are denied.

TWENTY-FIRST: In answer to paragraph 21, BMS admits that in 2003 the *Canadian Adverse Reaction Newsletter* issued a report on Tequin® and hypoglycemia and hyperglycemia, BMS denies any attempt to characterize the referenced 2003 *Canadian Adverse Reaction Newsletter* and further denies the allegations of paragraph 21 to the extent they might be deemed to allege that the adverse events alleged were caused by Tequin®. BMS denies the remaining allegations of paragraph 21.

TWENTY-SECOND: Answering the allegations of paragraph 22, BMS admits that, after consultation with and approval by the Food and Drug Administration, changes to the Tequin® label were made at various times to reflect post market information received regarding adverse events temporally associated with Tequin® and for which a causal relationship has not been established and states that both the United States and Japanese labels speak for themselves.

TWENTY-THIRD: The allegations of paragraph 23 are denied.

TWENTY-FOURTH: The allegations of paragraph 24 are denied.

TWENTY-FIFTH: In answer to paragraph 25, BMS admits that in November 2004 a study by Frothingham was published entitled *Glucose Homeostasis Abnormalities Associated with Use of Gatifloxacin*, BMS denies any attempt to characterize the referenced Frothingham study and denies that the findings of the study have been proven to a reasonable degree of scientific certainty.

TWENTY-SIXTH: The allegations of paragraph 26 are denied as alleged except BMS admits that it manufactured, sold and distributed Tequin® (Gatifloxacin) in accordance with its Food and Drug Administration approved labeling.

TWENTY-SEVENTH: The allegations of paragraph 27 are denied.

TWENTY-EIGHTH: In answer to paragraph 28, BMS admits that in March 2006 a study by Park-Wyllie was published relating to Tequin®, BMS denies any attempt to characterize the referenced Park-Wyllie study and denies that the findings of the study have been proven to a reasonable degree of scientific certainty.

TWENTY-NINTH: The allegations of paragraph 29 are denied as alleged except BMS admits that it manufactured, sold and distributed Tequin® (Gatifloxacin) in accordance with its Food and Drug Administration approved labeling.

THIRTIETH: The allegations of paragraph 30 are denied.

THIRTY-FIRST: The allegations of paragraph 31 are denied.

THIRTY-SECOND: The allegations of paragraph 32 are denied for lack of sufficient information to justify a belief therein. Defendant respectfully refers to the medical records and pharmacy records for plaintiff as to the circumstances surrounding the medical care and treatment rendered and plaintiff's alleged use of the product.

THIRTY-THIRD: The allegations of paragraph 33 are denied to the extent that plaintiff contends that BMS is responsible for any alleged injury experienced by the plaintiff, and denied for lack of sufficient information to justify a belief concerning plaintiff's

medical treatment. Defendant respectfully refers to the medical records and pharmacy records for plaintiff as to the circumstances surrounding the medical care and treatment rendered and plaintiff's alleged use of the product.

THIRTY-FOURTH: The allegations of paragraph 34 are denied to the extent that plaintiff contends that BMS is responsible for any alleged injury experienced by the plaintiff, and denied for lack of sufficient information to justify a belief concerning plaintiff's medical treatment. Defendant respectfully refers to the medical records and pharmacy records for plaintiff as to the circumstances surrounding the medical care and treatment rendered and plaintiff's alleged use of the product.

THIRTY-FIFTH: The allegations of paragraph 35 are denied to the extent that plaintiff contends that BMS is responsible for any alleged injury experienced by the plaintiff, and denied for lack of sufficient information to justify a belief concerning plaintiff's medical treatment. Defendant respectfully refers to the medical records and pharmacy records for plaintiff as to the circumstances surrounding the medical care and treatment rendered and plaintiff's alleged use of the product.

THIRTY-SIXTH: The allegations of paragraph 36 are denied.

THIRTY-SEVENTH: The allegations of paragraph 37 are denied to the extent that plaintiff contends that BMS is responsible for any alleged damages sustained by the plaintiff.

THIRTY-EIGHTH: The allegations of paragraph 38 are denied.

THIRTY-NINTH: The allegations of paragraph 39 are denied.

AS AND FOR AN ANSWER TO COUNT I
STRICT LIABILITY IN VIOLATION OF ARKANSAS CODE § 16-116-101, et seq.

FORTIETH: Answering the allegations of paragraphs 1 through 39, defendant repeats and incorporates by reference its responses to all preceding paragraphs of this answer as if fully set forth at length herein.

FORTY-FIRST: The allegations of paragraph 41 are denied.

FORTY-SECOND: The allegations of paragraph 42 are denied.

FORTY-THIRD: The allegations of paragraph 43 are denied for lack of sufficient information to justify a belief therein. Defendant respectfully refers to the medical records and pharmacy records for plaintiff as to the circumstances surrounding the medical care and treatment rendered and plaintiff's alleged use of the product.

FORTY-FOURTH: The allegations of paragraph 44 are denied.

FORTY-FIFTH: The allegations of paragraph 45 are denied.

FORTY-SIXTH: The allegations of paragraph 46 are denied as alleged except that BMS admits that it sold Tequin® (Gatifloxacin) for various uses in accordance with its Food and Drug Administration approved labeling in the State of Arkansas and elsewhere and refers to the Food and Drug Administration approved Tequin® labeling for information concerning approved product indications.

FORTY-SEVENTH: The allegations of paragraph 47 are denied.

FORTY-EIGHTH: The allegations of paragraph 48 are denied.

FORTY-NINTH: The allegations of paragraph 49 are denied as alleged except BMS admits that it manufactured, sold and distributed Tequin® (Gatifloxacin) in accordance with its Food and Drug Administration approved labeling.

FIFTIETH: The allegations of paragraph 50 are denied.

FIFTY-FIRST: The allegations of paragraph 51 are denied.

FIFTY-SECOND: The allegations of paragraph 52 are denied as alleged except BMS admits that it manufactured, sold and distributed Tequin® (Gatifloxacin) in accordance with its Food and Drug Administration approved labeling.

FIFTY-THIRD: The allegations of paragraph 53 are denied.

FIFTY-FOURTH: The allegations and all subparts of paragraph 54 are denied.

FIFTY-FIFTH: The allegations of paragraph 55 are denied.

FIFTY-SIXTH: BMS makes no response to the allegations contained in paragraph 56 of plaintiff's Complaint which are purely of a legal nature and refers all issues of law to the Court. To the extent an answer is required, the allegations of paragraph 56 are denied as alleged, except BMS admits that all parties request a jury trial.

AS AND FOR AN ANSWER TO COUNT II
NEGLIGENCE

FIFTY-SEVENTH: Answering the allegations of paragraphs 1 through 56, defendant repeats and incorporates by reference its responses to all preceding paragraphs of this answer as if fully set forth at length herein.

FIFTY-EIGHTH: The allegations of paragraph 58 are denied.

FIFTY-NINTH: The allegations of paragraph 59 are denied.

SIXTIETH: The allegations of paragraph 60 are denied as alleged except BMS admits that it manufactured, sold and distributed Tequin® (Gatifloxacin) in accordance with its Food and Drug Administration approved labeling.

SIXTY-FIRST: The allegations and all subparts of paragraph 61 are denied.

SIXTY-SECOND: The allegations of paragraph 62 are denied.

SIXTY-THIRD: The allegations of paragraph 63 are denied.

SIXTY-FOURTH: BMS makes no response to the allegations contained in paragraph 64 of plaintiff's Complaint which are purely of a legal nature and refers all issues of law to the Court. To the extent an answer is required, the allegations of paragraph 64 are denied as alleged, except BMS admits that all parties request a jury trial.

AS AND FOR AN ANSWER TO COUNT III
BREACH OF IMPLIED WARRANTY OF FITNESS

SIXTY-FIFTH: Answering the allegations of paragraphs 1 through 64, defendant repeats and incorporates by reference its responses to all preceding paragraphs of this answer as if fully set forth at length herein.

SIXTY-SIXTH: The allegations of paragraph 66 are denied.

SIXTY-SEVENTH: The allegations of paragraph 67 are denied.

SIXTY-EIGHTH: The allegations of paragraph 68 are denied.

SIXTY-NINTH: The allegations of paragraph 69 are denied.

SEVENTIETH: The allegations of paragraph 70 are denied.

SEVENTY-FIRST: The allegations of paragraph 71 are denied.

SEVENTY-SECOND: The allegations of paragraph 72 are denied.

SEVENTY-THIRD: BMS makes no response to the allegations contained in paragraph 73 of plaintiff's Complaint which are purely of a legal nature and refers all issues of law to the Court. To the extent an answer is required, the allegations of paragraph 73 are denied as alleged, except BMS admits that all parties request a jury trial.

**AS AND FOR AN ANSWER TO COUNT III
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

SEVENTY-FOURTH: Answering the allegations of paragraphs 1 through 73, defendant repeats and incorporates by reference its responses to all preceding paragraphs of this answer as if fully set forth at length herein.

SEVENTY-FIFTH: The allegations of paragraph 75 are denied.

SEVENTY-SIXTH: The allegations of paragraph 76 are denied as alleged except BMS admits that it manufactured, sold and distributed Tequin® (Gatifloxacin) in accordance with its Food and Drug Administration approved labeling and that Tequin® (Gatifloxacin) is an antibacterial agent.

SEVENTY-SEVENTH: The allegations of paragraph 77 are denied.

SEVENTY-EIGHTH: The allegations of paragraph 78 are denied.

SEVENTY-NINTH: The allegations of paragraph 79 are denied.

EIGHTIETH: The allegations of paragraph 80 are denied.

EIGHTY-FIRST: The allegations of paragraph 81 are denied.

EIGHTY-SECOND: The allegations of paragraph 82 are denied as alleged except BMS admits that it manufactured, sold and distributed Tequin® (Gatifloxacin) in accordance with its Food and Drug Administration approved labeling.

EIGHTY-THIRD: The allegations of paragraph 83 are denied for lack of sufficient information to justify a belief therein. Defendant respectfully refers to the medical

records and pharmacy records for plaintiff as to the circumstances surrounding the medical care and treatment rendered and plaintiff's alleged use of the product.

EIGHTY-FOURTH: The allegations of paragraph 84 are denied.

EIGHTY-FIFTH: The allegations of paragraph 85 are denied.

EIGHTY-SIXTH: The allegations of paragraph 86 are denied.

EIGHTY-SEVENTH: BMS makes no response to the allegations contained in paragraph 87 of plaintiff's Complaint which are purely of a legal nature and refers all issues of law to the Court. To the extent an answer is required, the allegations of paragraph 87 are denied as alleged, except BMS admits that all parties request a jury trial.

**AS AND FOR AN ANSWER TO COUNT V
FRAUDULENT MISREPRESENTATION**

EIGHTY-EIGHTH: Answering the allegations of paragraphs 1-87 defendant repeats and incorporates by reference its responses to all preceding paragraphs of this answer as if fully set forth at length herein.

EIGHTY-NINTH: The allegations of paragraph 89 are denied.

NINETIETH: The allegations of paragraph 90 are denied.

NINETY-FIRST: The allegations of paragraph 91 are denied.

NINETY-SECOND: The allegations of paragraph 92 are denied.

NINETY-THIRD: The allegations of paragraph 93 are denied.

NINETY-FOURTH: The allegations of paragraph 94 are denied.

NINETY-FIFTH: The allegations of paragraph 95 are denied.

NINETY-SIXTH: The allegations of paragraph 96 are denied.

NINETY-SEVENTH: The allegations and all subparts of paragraph 97 are denied.

NINETY-EIGHTH: The allegations of paragraph 98 are denied.

NINETY-NINTH: The allegations of paragraph 99 are denied.

ONE HUNDREDTH: The allegations of paragraph 100 are denied.

ONE HUNDRED FIRST: The allegations of paragraph 101 are denied.

ONE HUNDRED SECOND: The allegations of paragraph 102 are denied.

ONE HUNDRED THIRD: The allegations of paragraph 103 are denied.

ONE HUNDRED FOURTH: The allegations of paragraph 104 are denied.

ONE HUNDRED FIFTH: The allegations of paragraph 105 are denied.

ONE HUNDRED SIXTH: BMS makes no response to the allegations contained in paragraph 106 of plaintiff's Complaint which are purely of a legal nature and refers all issues of law to the Court. To the extent an answer is required, the allegations of paragraph 106 are denied as alleged, except BMS admits that all parties request a jury trial.

**AS AND FOR AN ANSWER TO COUNT VI
FRAUDULENT CONCEALMENT**

ONE HUNDRED SEVENTH: Answering the allegations of paragraphs 1-106, defendant repeats and incorporates by reference its responses to all preceding paragraphs of this answer as if fully set forth at length herein.

ONE HUNDRED EIGHTH: The allegations of paragraph 108 are denied.

ONE HUNDRED NINTH: The allegations and all subparts of paragraph 109 are denied.

ONE HUNDRED TENTH: The allegations of paragraph 110 are denied.

ONE HUNDRED ELEVENTH: The allegations of paragraph 111 are denied.

ONE HUNDRED TWELFTH: The allegations of paragraph 112 are denied.

ONE HUNDRED THIRTEENTH: The allegations of paragraph 113 are denied.

ONE HUNDRED FOURTEENTH: The allegations of paragraph 114 are denied.

ONE HUNDRED FIFTEENTH: The allegations of paragraph 115 are denied.

ONE HUNDRED SIXTEENTH: The allegations of paragraph 116 are denied.

ONE HUNDRED SEVENTEENTH: The allegations of paragraph 117 are denied.

ONE HUNDRED EIGHTEENTH: BMS makes no response to the allegations contained in paragraph 118 of plaintiff's Complaint which are purely of a legal nature and refers

all issues of law to the Court. To the extent an answer is required, the allegations of paragraph 118 are denied as alleged, except BMS admits that all parties request a jury trial.

AS AND FOR AN ANSWER TO COUNT VII
INTENTIONAL INFILCTION OF EMOTIONAL DISTRESS

ONE HUNDRED NINETEENTH: Answering the allegations of paragraphs 1-118, defendant repeats and incorporates by reference its responses to all preceding paragraphs of this answer as if fully set forth at length herein.

ONE HUNDRED TWENTIETH: The allegations and all subparts of paragraph 120 are denied.

ONE HUNDRED TWENTY-FIRST: The allegations of paragraph 121 are denied.

ONE HUNDRED TWENTY-SECOND: The allegations of paragraph 122 are denied.

ONE HUNDRED TWENTY-THIRD: The allegations of paragraph 123 are denied.

ONE HUNDRED TWENTY-FOURTH: The allegations of paragraph 124 are denied.

ONE HUNDRED TWENTY-FIFTH: BMS makes no response to the allegations contained in paragraph 125 of plaintiff's Complaint which are purely of a legal nature and refers all issues of law to the Court. To the extent an answer is required, the allegations of paragraph 125 are denied as alleged, except BMS admits that all parties request a jury trial.

AS AND FOR AN ANSWER TO COUNT VIII
VIOLATION OF ARKANSAS CONSUMER PROTECTION ACT/
DECEPTIVE TRADE PRACTICES

ONE HUNDRED TWENTY-SIXTH: Answering the allegations of paragraphs 1-125, defendant repeats and incorporates by reference its responses to all preceding paragraphs of this answer as if fully set forth at length herein.

ONE HUNDRED TWENTY-SEVENTH: The allegations of paragraph 127 are denied.

ONE HUNDRED TWENTY-EIGHTH: The allegations and all subparts of paragraph 128 are denied.

ONE HUNDRED TWENTY-NINTH: The allegations of paragraph 129 are denied.

ONE HUNDRED THIRTIETH: The allegations of paragraph 130 are denied.

ONE HUNDRED THIRTY-FIRST: BMS makes no response to the allegations contained in paragraph 131 of plaintiff's Complaint which are purely of a legal nature and refers all issues of law to the Court. To the extent an answer is required, the allegations of paragraph 131 are denied as alleged, except BMS admits that all parties request a jury trial.

AS AND FOR AN ANSWER TO
PUNITIVE DAMAGES

ONE HUNDRED THIRTY-SECOND: Answering the allegations of paragraphs 1-131, defendant repeats and incorporates by reference its responses to all preceding paragraphs of this answer as if fully set forth at length herein.

ONE HUNDRED THIRTY-THIRD: The allegations and all subparts of paragraph 133 are denied.

ONE HUNDRED THIRTY-FOURTH: The allegations of paragraph 134 are denied.

ONE HUNDRED THIRTY-FIFTH: BMS makes no response to the allegations contained in paragraph 135 of plaintiff's Complaint which are purely of a legal nature and refers all issues of law to the Court. To the extent an answer is required, the allegations of paragraph 135 are denied as alleged, except BMS admits that all parties request a jury trial.

**AS AND FOR AN ANSWER TO
PLAINTIFF'S DAMAGES**

ONE HUNDRED THIRTY-SIXTH: The allegations and all subparts of paragraph 136 are denied.

ONE HUNDRED THIRTY-SEVENTH: BMS makes no response to the allegations contained in paragraph 137 of plaintiff's Complaint which are purely of a legal nature and refers all issues of law to the Court. To the extent an answer is required, the allegations of paragraph 137 are denied as alleged, except BMS admits that all parties request a jury trial.

AS AND FOR A FIRST AFFIRMATIVE DEFENSE

That one or more of the causes of action are time barred pursuant to the applicable Statute of Limitations.

AS AND FOR A SECOND AFFIRMATIVE DEFENSE

Defendant specifically pleads estoppel, waiver, ratification, laches, accord and satisfaction, and failure to mitigate or minimize damages, if any.

AS AND FOR A THIRD AFFIRMATIVE DEFENSE

Any alleged negligent or culpable conduct of defendant, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of plaintiff's alleged injuries.

AS AND FOR A FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because Tequin® (Gatifloxacin) was designed, manufactured, marketed, and labeled with proper warnings, information, cautions, and instructions, in accordance with the state of the art and the state of scientific and technological knowledge. Defendant invokes all state of the art defenses applicable to plaintiff's claims, including the state of the art applicable to the industry in question, medicine, medical science, and all others, alleging that they discharged, according to law and due care, each and every duty which plaintiff may have been owed.

AS AND FOR A FIFTH AFFIRMATIVE DEFENSE

That any injuries which plaintiff may have sustained at the time and place set forth in the complaint herein and which resulted in his injuries therein alleged were caused in whole or in part by the contributory negligence and/or culpable conduct of the plaintiff and not as a result of any contributory negligence and/or culpable conduct on the part of defendant.

AS AND FOR A SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by the doctrine(s) contained in Restatement (Second) of Torts § 402A, Comment k.

AS AND FOR A SEVENTH AFFIRMATIVE DEFENSE

To the extent that plaintiff alleges that defendant failed to warn of known or knowable risks inherent in the use of its product, such claims are governed by the learned intermediary or informed intermediary rule or doctrine.

AS AND FOR AN EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because plaintiff's injuries, if any, were the result of conduct of plaintiff, independent third parties over which defendant had no control, or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening, and superseding causes of the alleged injuries, including, but not limited to plaintiff's pre-existing medical conditions.

AS AND FOR A NINTH AFFIRMATIVE DEFENSE

Plaintiff's claims of product defect are, or may be barred by Section 4 of the Restatement (Third) of Torts: Products Liability because BMS' products complied with applicable product safety statutes and administrative regulations.

AS AND FOR A TENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because defendant complied with all federal and state statutes as well as all administrative regulations.

AS AND FOR AN ELEVENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because Tequin® (Gatifloxacin) is comprehensively regulated by the United States Food and Drug Administration pursuant to the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 et seq., and regulations and orders promulgated thereunder. Accordingly, plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

AS AND FOR A TWELFTH AFFIRMATIVE DEFENSE

Defendant has no legal relationship or privity with plaintiff and owes no duty to plaintiff by which liability could be attributed to it as it relates to the attempted causes of action for breach of any warranties.

AS AND FOR A THIRTEENTH AFFIRMATIVE DEFENSE

Defendant made no warranties of any kind, express or implied, or any representations of any nature whatsoever to plaintiff. If any such warranties were made, whether express or implied, which defendant specifically denies, such claims are barred due to lack of privity with defendant, and/or for failure of plaintiff to give timely notice of any alleged breach of warranty, and by reason of disclaimers.

AS AND FOR A FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred because the use of Tequin® (Gatifloxacin) was generally recognized as safe and effective pursuant to conditions established by the Food and Drug Administration and applicable regulations, including packaging and labeling regulations.

AS AND FOR A FIFTEENTH AFFIRMATIVE DEFENSE

Tequin® (Gatifloxacin) was, and is, safe for its intended use and was, and is, not defective or unreasonably dangerous.

AS AND FOR A SIXTEENTH AFFIRMATIVE DEFENSE

The conduct of defendant in all activities with respect to the subject product has been and is under the supervision of the Food and Drug Administration. Accordingly, this action is barred by the Doctrine of Primary Jurisdiction.

AS AND FOR A SEVENTEENTH AFFIRMATIVE DEFENSE

Although defendant denies that plaintiff is entitled to judgment in any amount against it, defendant would show that any judgment against it is limited to the applicable amount or percentage of its liability.

AS AND FOR AN EIGHTEENTH AFFIRMATIVE DEFENSE

Defendant is not liable for any injuries or damages plaintiff may have incurred as a consequence of any use of defendant's products not specifically authorized in written information accompanying its products in accordance with applicable law.

AS AND FOR A NINETEENTH AFFIRMATIVE DEFENSE

Defendant hereby gives notice that, to the extent the sophisticated purchaser doctrine is applicable to any of the allegations contained in the complaint, defendant intends to rely upon the same in defense of this action.

AS AND FOR A TWENTIETH AFFIRMATIVE DEFENSE

Defendant hereby specifically denies each and every allegation contained in the complaint by which liability is sought to be imposed upon them and gives notice that it intends to rely upon such other affirmative defenses as may become available or known to it during the course of disclosure and discovery, and it reserves the right to amend this answer to assert any such defenses.

AS AND FOR A TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims are barred by Section 6(c) and (d) of the Restatement (Third) of Torts: Products Liability. Reasonable physicians knowing of the reasonably foreseeable risks and therapeutic benefits associated with defendant's product would have prescribed and did prescribe its product for classes of patients. In addition, defendant provided reasonable instructions or warnings to prescribing physicians.

AS AND FOR A TWENTY-SECOND AFFIRMATIVE DEFENSE

The injuries and/or damages of plaintiff (if any) were the result of unavoidable circumstances that could not have been prevented by anyone.

AS AND FOR A TWENTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff's complaint fails to state a claim against the defendant upon which relief can be granted.

AS AND FOR A TWENTY-FOURTH AFFIRMATIVE DEFENSE

The public interest and benefit and the availability of such product that is the subject matter of this action preclude liability for risks, if any, resulting from such activities, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to plaintiff's claims, if it is determined that there is a risk inherent in any said product, then such risk is outweighed by the benefits of the product.

AS AND FOR A TWENTY-FIFTH AFFIRMATIVE DEFENSE

If plaintiff suffered injuries and damages by reason of operation of nature or idiosyncratic and/or allergic reaction to defendant's products, used either alone or in combination with any other drug, the defendant is not liable.

AS AND FOR A TWENTY-SIXTH AFFIRMATIVE DEFENSE

If plaintiff sustained injuries or incurred expenses as alleged, such injuries or expenses resulted from pre-existing or unrelated medical, genetic or environmental conditions, diseases or illnesses of the plaintiff that were unrelated to any of the conduct of, or products placed in the stream of commerce by defendant.

AS AND FOR A TWENTY-SEVENTH AFFIRMATIVE DEFENSE

Any verdict or judgment rendered against defendant must be reduced by those amounts which have been, or will, with reasonable certainty, replace or indemnify plaintiff, in whole or in

part, for any past or future claimed economic loss, from any collateral source such as insurance, social security, worker's compensation, or employee benefit programs.

AS AND FOR A TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Upon information and belief, plaintiff had full knowledge of the risks and possible adverse effects pertaining to ingestion and use of the alleged product, and part or all of the injuries, damages, and/or losses (if any) sustained by plaintiff arose from and were caused by such risks of which he was aware, and such risks were accepted and assumed by the plaintiff, and for that reason plaintiff's recovery (if any) should be diminished, reduced, offset or barred in accordance with the principles of assumption of risk and/or informed consent.

AS AND FOR A TWENTY-NINTH AFFIRMATIVE DEFENSE

The product at issue was only available through the prescription of licensed physicians who were provided complete and adequate warnings and instructions consistent with the state of medical and scientific knowledge at the time.

AS AND FOR A THIRTIETH AFFIRMATIVE DEFENSE

Part of the damages alleged by plaintiff arising out of plaintiff's injuries is due to plaintiff's failure to mitigate his damages as required by law and therefore, may not be recovered by plaintiff in this action.

AS AND FOR A THIRTY-FIRST AFFIRMATIVE DEFENSE

The product of which plaintiff complains has certain unavoidable, inherent characteristics that cannot be obviated under the state of scientific knowledge existing at the time such product was manufactured. While denying that such characteristics are dangerous or defective as a matter of law, if plaintiff sustained any injuries as a result of using or exposure to this product at issue, those injuries were the result of properties necessarily associated with the product that were unavoidable and for which defendant cannot be held responsible.

AS AND FOR A THIRTY-SECOND AFFIRMATIVE DEFENSE

To the extent plaintiff is seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

AS AND FOR A THIRTY-THIRD AFFIRMATIVE DEFENSE

There is no basis for asserting independent liability against Schering Corporation. Accordingly, the Complaint against Schering Corporation should be dismissed.

AS AND FOR A THIRTY-FOURTH AFFIRMATIVE DEFENSE

Contingent upon the completion of discovery and to the extent applicable, defendant reserves the right to file such additional defenses as may be appropriate.

AS AND FOR A THIRTY-FIFTH AFFIRMATIVE DEFENSE

Venue is improper, or, alternatively, more convenient in another forum.

WHEREFORE, defendant, Bristol-Myers Squibb Company, demands judgment dismissing plaintiff's complaint and all cross-claims with prejudice, with its costs, disbursements, attorneys' fees, and for such other and further relief as to this Court may seem just and proper.

JURY DEMAND

Defendant demands a trial by jury as to all issues so triable.

Dated: New York, New York
October 5, 2007

Respectfully Submitted,

SEDGWICK, DETERT, MORAN, & ARNOLD LLP

By: 
MATTHEW J. McCAULEY (MM-9610)

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